Remarks

I. Status of the Claims

Upon entry of the foregoing amendments claims 1-9 will be pending and claim 1 will have been amended. Applicants have made non-narrowing amendments to claim 1 merely to reflect election of Group 1, SEQ ID NO 1 and to clarify the language of the claim. No new matter has been added by this amendment.

In addition, Applicants note that the Examiner has acknowledged the election, with traverse, of Group 1, SEQ ID NO 1. Accordingly, although not explicitly mentioned in the Office Action, Applicants understand that claims 2-9 are withdrawn from consideration as drawn to non-elected subject matter as provided in MPEP § 821.01. In view of the following remarks, reconsideration and allowance are respectfully requested.

II. Response to Rejection Under 35 U.S.C. § 101

Claim 1 has been rejected under 35 U.S.C. § 101, for allegedly lacking a patentable utility. Applicants respectfully traverse this rejection.

The Examiner alleges that the claimed subject matter is not supported by a credible, specific, and substantial utility because the specification only states that the cDNA compound is useful as a probe for obtaining a full length coding sequence or a gene, which could be used to make a protein. The Examiner further alleges that the specification does not disclose a specific asserted utility for the protein and that the specification merely sets forth research contemplated by Applicants to establish a utility for the protein. The Examiner concludes that because the specification allegedly only discloses that the claimed invention can be used to produce a product

of unknown function, the claimed invention has no asserted or well known patentable utility. Applicants respectfully disagree.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 USC § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 U.S.P.Q.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The Examiner acknowledges that the specification describes a utility for the present invention including the use of the "cDNA compound [] as a probe for obtaining the full length coding sequence or the gene, which would be used to make protein." *Office Action mailed February 17, 2002* at page 2. In addition to this utility described by the Examiner (quoted above), the invention is useful for detecting the presence and level of mRNA in a sample; identifying polymorphisms; obtaining promoters and other flanking genetic elements to such molecules; determining whether a plant has a mutation affecting the expression response of the plant; determining the location of a corresponding DNA sequence on a genetic map; isolating related nucleic acid and protein molecules; and conducting plant transformation or transfection; *etc.* (*see, e.g., Specification* beginning at page 28, under heading "Uses of the Agents of the Invention").

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits. Any of these utilities alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 USC § 101, and they have done so in the present case, the premise of the rejection under Section 101 is incorrect, and withdrawal of the rejection is respectfully requested.

Surprisingly, the Examiner notes that the credibility of the presently asserted utilities has not been assessed. *Office Action mailed February 17, 2002* at page 3. However, this is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the

initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 122, 1225-26, 187 U.S.P.Q. 664, 666 (CCPA 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided").

The Examiner has set forth no factual reasons which would lead one skilled in the art to question the objective truth of the operability of the numerous utilities disclosed in the specification. More particularly, one of the utilities disclosed in the specification is use of the claimed nucleic acid molecule to identify the presence or absence of a polymorphism. The Examiner provides no support (legal or factual) that this utility, or any of the asserted utilities, is not specific or substantial.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. However, the fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing

techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." *MPEP* § 2107 at page 2100-25.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[1] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 USC § 101.

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, *Arabidopsis*,

[1] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

barley, cotton, oat, oilseed rape, rice, *etc.*[2] *See Specification* at page 29, lines 24-29. Another illustrative example of a molecule that can be isolated using the claimed nucleic acid molecules is the promoter of the gene corresponding to the claimed nucleic acid molecules. Further, Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. *See Specification* at page 31, line 1-6. The Examiner has provided no evidence that would reasonably suggest that any of these cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d at 1567.

Further, it is noted that a utility is not legally insufficient simply because other molecules can be used for the same purpose. There is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See* Diamond *v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

[2] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

The claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a unique subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 USC §101.

The Examiner also asserts that the present invention lacks legally sufficient utility because the numerous utilities disclosed are not "substantial". The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v.* Wattanasin, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing "real world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (CCPA 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use"). *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (CCPA 1974).

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (CCPA 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Compare Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and

development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

In view of the above, Applicants submit that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 USC §101 is improper, and withdrawal of the rejection is respectfully requested.

III. Response to Rejection Under 35 U.S.C. § 112, First Paragraph

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification because the claimed invention allegedly lacks utility (i.e., an invention without utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

In the Office Action, at pages 3-4, claim 1 has also been rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Applicants respectfully traverse this rejection.

The Examiner asserts that Applicants have not adequately described the claimed nucleic acid that encodes a wheat protein or fragment thereof comprising SEQ ID NO: 1. According to the Examiner, the specification only describes an EST which has SEQ ID NO: 1 and does not teach the function of a protein encoded by isolated SEQ ID NO 1 or any description of the

remainder of the coding sequence. Allegedly, the structure of the full-length coding sequence is completely unknown from the specification and there is no description of what type of protein SEQ ID NO: 1 might be encoding. Therefore, the Examiner concludes, the specification does not support Applicants' possession of a nucleic acid encoding a wheat protein at the time of filing.

Applicants submit that the specification provides an adequate written description of the claimed invention. Adequate written description of a claimed genus can be achieved by "recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). Furthermore, adequate written description merely requires that "[t]he feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members." *Id* (emphasis added). The specification provides adequate written description for the claimed invention, because features of the claimed purified nucleic acid molecule genus, for example, the recited nucleotide sequence, distinguish the claimed genus from unclaimed purified nucleotide molecules, which do not include the recited nucleotide sequence SEQ ID NO: 1.

In contrast to the mere name "cDNA" provided in *Eli Lilly*, Applicants have provided a detailed chemical structure by way of the claimed SEQ ID NO: 1. Applicants have therefore satisfied the *Eli Lilly* test for written description.

The claimed nucleic acid molecules are a genus of nucleic acid molecules having a common structural feature of a particular enumerated nucleotide sequence, *i.e.*, SEQ ID NO: 1. The respective common structural feature (the nucleotide sequence) is shared by every nucleic

acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not. One skilled in the art would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences.

As such, it is respectfully submitted that a person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, understand that Applicants had possession of a nucleic acid molecule including SEQ ID NO: 1, and therefore, had possession of the claimed invention. The use of open claiming language (comprising) or semi-open claiming (consisting essentially of) does not alter the fact that a skilled artisan would readily envision adequate written description support for the claimed invention. It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (BPAI 1948). The fact that nucleic acid sequences may be added to either end of the recited sequence is beside the point. Applicants have reasonably conveyed possession of the claimed invention to one skilled in the art, even when additional sequences are added to either end.

Indeed, the present application describes more than just the nucleotide sequence required by the claim (SEQ ID NO: 1). For example, it describes vectors comprising the claimed nucleic

acid molecules. *See Specification* at page 53, line 6 through page 59, line 26. Furthermore, the addition of extra nucleotides or detectable labels to the claimed nucleotide sequence (SEQ ID NO: 1) is readily envisioned by one of ordinary skill in the art upon reading the present specification.[3] *See, e.g., Specification* at page 15, lines 6-10 (describing sequences with labels to facilitate detection).

For at least these reasons, it is submitted that claim 1 meets the written description requirement under 35 U.S.C. §112, first paragraph, and withdrawal of this rejection is respectfully requested.

IV. Summary

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

[3] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

IN THE CLAIMS:

Please amend claim 1 as follows:

1. A substantially purified nucleic acid molecule that encodes a wheat protein or fragment [thereof] of a wheat protein comprising [a] nucleic acid sequence [selected from the group consisting of] SEQ ID NO: 1 [through SEQ ID NO: 10952].